

Remarks/ Arguments

This Response is submitted in response to the Office communication dated July 8, 2009 (hereinafter, the "Office Action"), in connection with the above-identified application ("application"). The Office communication provided a three month shortened statutory period in which to respond, ending on October 8, 2009. Submitted herewith is a One-Month Petition For Extension of Time extending the due date to November 9, 2009. Accordingly, this Response is timely submitted.

Claims 1-9 were elected for prosecution in response to the restriction requirement mailed on March 31, 2009. Claims 10-16 are withdrawn from consideration as a result of their non-election in response to the restriction requirement mailed on March 31, 2009. Applicants reserve their right to seek rejoinder and/or to file related applications directed to the non-elected subject matter of Claims 10-16.

Applicants have amended Claims 1, 3, 10, 11, 12 and 13 and cancelled Claim 9, which when considered with the following remarks, is deemed to place the present application in condition for allowance. Claims 3, 11, 12 and 13 have been amended to correct obvious typographical errors. Claims 1, 10, 11, 12 and 13 have been amended to clarify that the ionic liquid used is a molten salt. Claim 1 has been further amended to specify that the ionic liquid is removed during the described method for preparing the microparticles. Support for the amendment to Claims 1, 10, 11, 12 and 13 may be found throughout the specification, for example in paragraph 3 of page 6, paragraphs 2 to 5 of page 10, and the examples of the original description and the original claims of the filed application. Accordingly, these claims are now in condition for allowance.

Applicants respectfully submit that the foregoing amendments to the claims and specification do not add any new matter.

Rejection under 35 U.S.C. §102

Claims 1-7 and 9 have been rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 762 211 to Iwamoto et al (hereinafter "Iwamoto et al").

Pursuant to 35 U.S.C. §102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), M.P.E.P. §2131. The identical invention must be shown in as complete detail as contained in ...the claims." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Applicants respectfully submit that amended Claims 1-7 are patentable under 35 U.S.C. §102(b) over Iwamoto et al. Claim 1 has been amended to clarify that the microparticles are prepared with the use of an ionic liquid which is a "molten salt". Claim 1 has been further amended to clarify that the used ionic liquid is removed to form the microparticles. Claim 9 has been cancelled.

The present invention is directed to a novel microparticle comprising at least one active agent embedded within a biocompatible, biodegradable polymeric matrix. This novel microparticle is prepared by a process requiring the combination of at least one active agent and the biocompatible, biodegradable polymer with an ionic liquid and then removing said ionic liquid. As used in the present invention, ionic liquids are specific classes of molten salts or mixtures of molten salts that typically have a vapor pressure of less than about 1 mm/Hg at 25°C.

Iwamoto et al describes a sustained release composition comprising a poly(lactic/glycolic) acid copolymer, a therapeutic agent and a quaternary ammonium surfactant prepared by the processes of microencapsulation, melt extrusion and melt pressing. Iwamoto et al discloses that the poly(lactic/glycolic) acid copolymer and the a quaternary ammonium surfactant together control the release rate of the therapeutic agent in the final composition. In contrast to the present invention, Iwamoto et al discloses the use of an ionic surfactant and does not teach or suggest any use of an ionic liquid which is a molten salt. Iwamoto et al further discloses a different preparation method which yields a different final product. In contrast to the present invention, Iwamoto et al discloses that their composition is prepared by technologies which incorporate the quaternary ammonium surfactant into the final product. Iwamoto et al does not teach or suggest any microparticles prepared by any method requiring removal of an ionic liquid which is a molten salt. Contrary to the Examiner's assertion, Iwamoto et al does not expressly or inherently teach or suggest each and every element of the claimed invention.

Applicants respectfully submit that dependent claims 2-7 are in condition for allowance as each claim depends from an allowable independent claim.

For the foregoing reasons, Applicants respectfully traverse and request withdrawal of the Examiner's rejection of claims 1-7 under 35 U.S.C. §102 over Iwamoto et al.

Rejection under 35 U.S.C. §103

Claims 1-9 have been rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the combined disclosures of Iwamoto et al in view of U.S. Patent No. 5,639,480 to Bodmer et al (hereinafter "Bodmer et al"). The Examiner has asserted that Iwamoto et al discloses the claimed invention with exception of the specific active agents set forth in dependent claim 8. However, the Examiner further asserts that Bodmer et al discloses active agents including peptides such as somatotropin or somastatin and thus that it would have been obvious to combine these peptides into the Iwamoto et al composition.

Graham v. John Deere Co. of Kansas City, 383 U. S. 1, 17-18 (1966), establishes an objective analysis for applying §103 to a question of obviousness: "the scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . ascertained; and the level of ordinary skill in the pertinent art resolved." The USPTO bears the burden of establishing a *prima facie* case of obviousness based on the results of the factual

inquiries under *Graham*. The *prima facie* case generally requires three showings: 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; 2) a reasonable expectation of success; and 3) that the prior art reference or combination of references teaches or suggests all the claim limitations. MPEP §2143.

Applicants respectfully submit that amended Claims 1-8 are patentable under 35 U.S.C. §103(a) over Iwamoto et al in view of Bodmer et al. Claim 9 has been cancelled.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established. One of the elements to establish a *prima facie* case of obviousness is that the combined references teach or suggest every claim limitation.

Applicants respectfully submit that amended Claims 1-9 are patentable under 35 U.S.C. §103(a) over Iwamoto et al and hereby incorporates by reference the detailed reasons set forth above in response to the Examiner's rejection under 35 U.S.C. §102(b).

Applicants respectfully submit that amended Claims 1-9 are patentable over Bodmer et al. One of the elements to establish a *prima facie* case of obviousness is that the combined references teach or suggest every claim limitation. In contrast to the present invention, Bodmer et al discloses the use of an anionic surfactant and does not teach or suggest any use of an ionic liquid which is a molten salt. Bodmer et al further discloses a different preparation method which yields a different final product. In contrast to the present invention, Bodmer et al discloses that their composition is prepared by a triple-emulsion procedure which incorporates the anionic surfactant into the final product. Bodmer et al does not teach or suggest any microparticles prepared by any method requiring removal of an ionic liquid which is a molten salt.

Without relying upon these teachings of the present application, one of ordinary skill would not have any motivation to modify Iwamoto et al in view of Bodmer et al to arrive at the claimed invention. Iwamoto et al and Bodmer et al use two different processing technologies to make pharmaceutical composition of two different therapeutic agents. One of ordinary skill would not ignore the teaching in Bodmer et al to use formulations prepared by an emulsion procedure and instead use one of Iwamoto's microencapsulation, melt extrusion and melt pressing technologies. Such modifications would require the teachings of the present application using impermissible hindsight.

Applicants further submit that amended Claims 1-8 are patentable under 35 U.S.C. §103 over Iwamoto et al in view of Bodmer et al since the cited references do not expressly or inherently teach or suggest each and every claim of the claimed invention. Neither Iwamoto et al nor Bodmer et al teach or suggest any microparticles prepared by any use of an ionic liquid which is a molten salt or any method requiring removal of an ionic liquid which is a molten salt as required in the claimed invention.

Applicants respectfully submit that dependent claims 2-8 are in condition for allowance as each claim depends from an allowable independent claim.

For the foregoing reasons, Applicants respectfully traverse and request withdrawal of the Examiner's rejection of claims 1-8 under 35 U.S.C. §103 over Iwamoto et al in view of Bodmer et al.

In view of the foregoing arguments Applicants respectfully request that the claims of the present application be reconsidered. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

Respectfully submitted,

Novartis Pharmaceuticals Corp.
Patents Pharma
One Health Plaza, Building 101
East Hanover, NJ 07936-1080
(862) 778-9949


Sandra S. Shim
Attorney for Applicant
Reg. No. 63,920

Date: October 19, 2009